DEVELOPMENT OF A HIGH DENSITY PERCUTANEOUS CONNECTOR SYSTEM

QUARTERLY REPORT #11
October 1999 – January 2000

Submitted to:
Bill Heetderks, M.D.
Project Officer
Neural Prosthesis Program
National Institutes of Health
Federal Building, Room 916
7550 Wisconsin Avenue
Bethesda, MD 20892

By:
PRIMARY CONTRACTOR: **BioElectric Corp.**
16125 S.W. 72nd Avenue Portland, OR 97224
503-639-3100

SUBCONTRACTOR: HUNTINGTON MEDICAL RESEARCH INSTITUTES
PI: Dr. William Agnew

Abstract

This report summarizes activity over the period from October 1999 through January 2000 on NIH Contract N01-DC-7-2103, "Development of a High Density Percutaneous Connector System". Six final implants are in cats at Huntington Medical Research Institute. These include the beaded skin attachment surface, low-leakage (electrical) cores, osseointegration and test cables. Additional testing has shown that the lower leakage reported last quarter is still not adequate, but that a new polymer reduces long-term leakage to less than 10 pA; the goal is 10 nA maximum. The quick disconnect mechanism has been fabricated and testing has begun.

CONTRIBUTORS:
Dr. LOU RUCKER, PRINCIPAL INVESTIGATOR
KEN MILLARD, ENGINEER
SOY TRUONG, ENGINEER TECHNICIAN
CHRIS POGATCHNIK, LASER TECHNOLOGY ENGINEER
JERRY BOOGAARD, MANAGER OF ADVANCED DEVELOPMENT LAB
JOHN SWANSON, MATERIALS ENGINEER
Dr. DAVE EDELL, CONSULTANT

I. Background and Review of Contract Requirements

This report summarizes activity during the specified quarter, on NIH Contract N01-DC--2103, "Development of a High Density Percutaneous Connector System". Over the course of this contract, a high density, planar, low profile connector system is being developed that incorporates pad grid array technology. This technology has unique advantages as applied to a percutaneous interconnect system. In particular the connector system will be low in profile, easy to clean, sealed against ingress of contaminants, offer low mechanical resistance to mating and demating and provide a very high number of contacts in a small diameter. The connector system will be implanted in a suitable animal model and the appropriate electrical, mechanical, and biocompatible properties of the system will be assessed. The specific technical requirements of this connector system as detailed in the contract are explained below:

- The connector will incorporate a pedestal that can be attached to the skull in a mechanically stable manner. The pedestal will be designed to accept a replaceable connector assembly. All materials of the pedestal in contact with tissue will be biocompatible and the profile of the pedestal will be low enough to minimize any physical trauma during mating and demating of the connector or due to normal physical activities.

- The connector assembly will be high-density with at least 70 contacts. The electrical isolation between the contacts or between the contacts and the body should withstand at least 18 volts without breakdown. The connector contacts when mated should be capable of passing up to 20 mA of current with less than a 1.0 volt drop across the connection. A simple method of mating and demating the upper and lower surfaces of the connector should be provided. In addition, a convenient means to attach electrical leads to the connector is needed.

- The connector will be designed from materials that are durable and can withstand the physical abuse from normal activities of daily living. The interface between the connector and the skin must be such that the passage of microorganisms into the body and fluid drainage out of the body is prevented.

- In earlier studies connectors had five separate loops of insulated wire, each 2 inches long. Because of wire breakage observed during these studies, it is necessary to make a more durable and a more realistic part. The present cable is a ribbon one-inch long with five 2-mil Pt/Ir wires, coated with Parylene and Silicone. The wires are looped so there are five loops for testing. The 2 mil wires are more rugged and easier to work with for initial tests, but 1 mil wires will be used after the ribbon cable concept is developed. An 18-Volt bias will be maintained on the wires relative to an implanted platinum wire connected to one of the unused contacts or the Ti connector body. The leakage current of the cable wires will be monitored with a maximum acceptable value of 10 nanoamperes.

- Performance of the connector system will be tested in a suitable animal model. After three to six months of implantation, the connector assembly will be explanted and gross and microscopic examinations will be performed to study the attachment of the pedestal to the skull, the attachment of the skin and soft tissue surrounding the pedestal to the pedestal wall and the reaction of adjacent tissue to the implanted device.

- Finally, design changes and improvements, if needed, will be recommended. A set of connectors will be fabricated and sent to the NIH for implantation. Initial testing will be in cats with final tests conducted in non-human primates.

II. HMRI Work

Huntington Medical Research Institute has implanted the final six connectors in cats. The objective is to maintain these implants for three months and then examine the skin attachment and osseointegration. Electrical leakage is being measured weekly during the experiment on all six animals. Three of the animals wear a bias pack that keeps the test cable conductors biased at 18 Volts relative to body tissue (the connector body). The other three are not being kept biased. The purpose is to discover if, in vivo, a drift mechanism (E-field) significantly adds or subtracts to the normal diffusion of water and ions into the polymers used in the connector.

III. Leakage Problems

In QPR number 9 the results of an almost year long study of leakage problems reported that leakage had been reduced, but was still not acceptable in a design that has been used successfully (< 1 nA leakage) for a number of years. The source of both moisture and ions is diffusion through polymers – both silicones and epoxy. The cause of leakage is voids in epoxy between the Alumna pieces used to align the pins and it was determined that the two-piece Alumna structure would be abandoned in favor of two structures: a solid core of modified EpoTek 301 and Alumna on the top surface backed by modified EpoTek 301. Four of the solid cores and two of the Alumna surfaces are used in the current HMRI implants. Some differences have been noted in the leakage levels, but are not yet conclusive.

During the last quarter in-vitro studies of leakage in polymers have been conducted. Modified EpoTek 301 has been used as the control with minor variations in the pin materials and more significant variation in the materials. The second material investigated is Ciba's Arocy XU 366, a cynate ester that is more hydrophobic than the 301 epoxy. The test pieces are 0.25 in square and approximately 0.130 inches thick to simulate the connector core. Two 0.020 inch holes are drilled 0.040 inch apart at the center of the pieces. Platinium-Iridium (10%) wire was placed in these holes to simulate the pins at the center of the connector. The top and bottom surfaces were mechanically polished and stainless steel wires with Tetraetch ® treated fluropolymer dielectrics were spot welded to the pins. The parts were sonicated using a four step process with detergent, rinse, methanol and IPA. Care was taken not to handle the top and bottom surfaces after

polishing and to use clean procedures after the cleaning. After cleaning, the top and bottom surfaces were covered with the EpoTek or Ciba material as appropriate in the final fabrication step. Leakage in the dry test parts was checked with 6 Volts and found to be less than 10 pA, essentially zero, in all cases. The parts were placed in Ringer's solution at 65 °C for a period of nine days. The leakage was again measured using 6 Volts with the following results:

Test Part Description	**Leakage**
1. Mod EpoTek that had been tested previously	200 nA
2. New mod EpoTek with PtIr pins	375 pA
3. New Ciba with PtIr pins	< 10 pA

As was shown in QPR 9, July 1999, the leakage at this temperature will reach an approximate steady state in six to nine days. The first two samples are similar in materials and structure so it might be expected that they would show similar leakage. However, the first test sample showed the higher leakage, more than an order of magnitude larger than the 5 nA found in complete connectors. It is thought that this excessive leakage is because of microfractures resulting from aging and multiple thermal cycles that would not occur in vivo. However, this does require additional investigation. Obviously the Ciba material raises hopes that a useful polymer can be found. This material cures to the required high durometer..

A second similar test will be performed starting in late February. It will be similar to the above except that more detailed data will be collected on four samples and the samples will be only 0.080 inches thick. The thickness is set by limitations in laser drilling Alumna. The polymer samples will be a similar thickness for comparison. The test samples will be:

1. Modified EpoTek 301
2. Ciba's Arocy 366
3. Solid Alumna with the Ciba material used as a seal (see below)

Pins will be placed 0.100 inches apart on a diagonal in all samples. Again, the spacing is determined by Alumna processing limits and is different than the 0.040 inches in the last samples. The polymer materials will have pins inserted, be polished, have wires spot welded, cleaned and capped as in the last test. The Alumna will be treated differently. A solid block of the material will have pins inserted with Ciba adhesive, the surfaces will be polished, wires attached and the materials will be cleaned. Caps of 0.020 inch thick Alumina with 0.020 inch holes 0.100 inches on the diagonal will be placed on the top and bottom as caps. The bottom will be rotated so the holes do not match the pin locations sealing this end of the pins. On top, the wires will exit the sample through the holes in the cap. Four samples can be tested simultaneously so two of the ceramic samples will be tested.

IV. Quick Disconnect

The quick disconnect (QD) design has been fabricated and are now being tested. A complete unit has not been assembled as adjustments are made in very tight tolerances. It is expected that complete units will be assembled in late February. A complete assembly is shown in Figure 1 showing the entire unit. At the bottom is the pedestal that will osseointegrate to the skull showing the cable exit. The cylinder above the pedestal is the percutaneous section with a skin attachment surface. This piece is modified to have a flange at the top to which three "claws" from the external unit will attach.

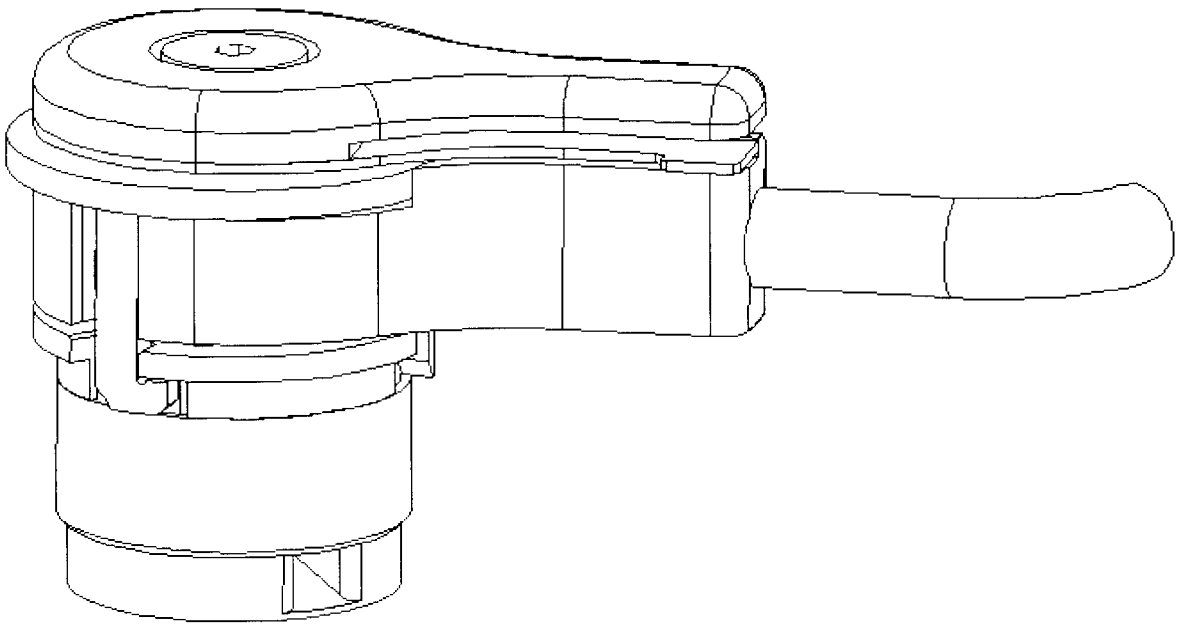
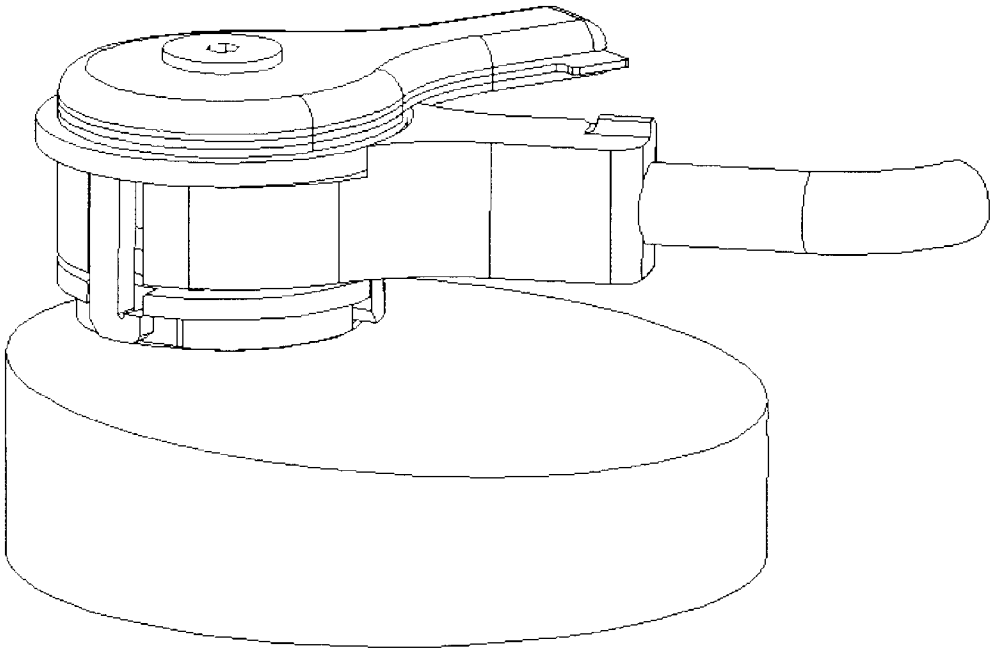


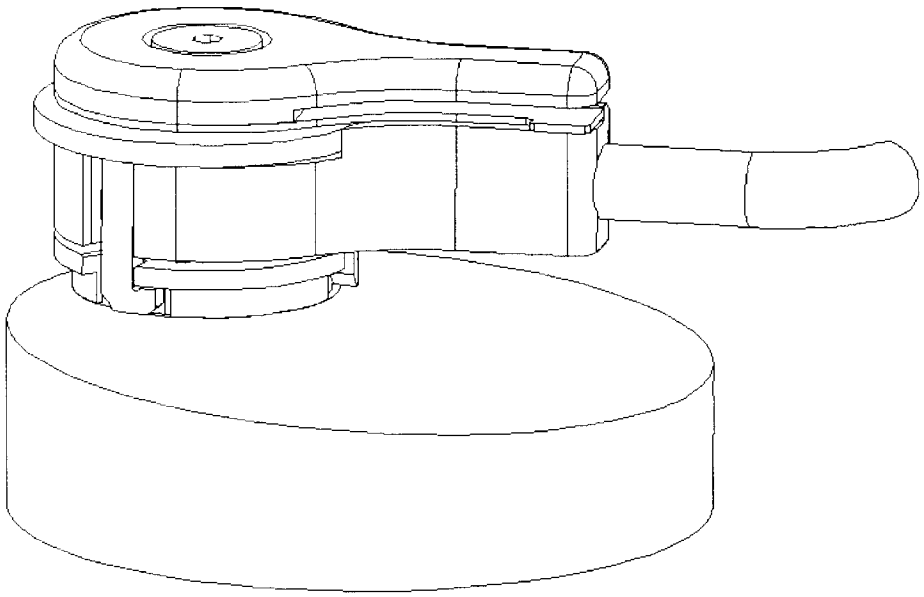
Figure 1. The complete quick disconnect assembly.

Figure 2 shows the external connector being attached to an implanted connector. Note the arm at the top is rotated open. Figure 3 has the are rotated into a locked position. Note that the claws have engaged the percutaneous part just above skin level (the large disk at the bottom represents skin).

Figure 3 shows the two sections separated for a more clear view. The upper section is no longer a pin grid array (PGA), but has a flex circuit with mating contacts across the bottom. Flex "wings" wrap up and around the side of the device where wires are attached to pads. The main structure of the upper section is a hollow cup on top of the flex circuit. Inside the hollow cup are bearings and surfaces used to tighten the claws on the lower section as the arm is rotated.



(a)



(b)

Figure 2. External assembly being attached.(a) shows the lock open and (b) shows it closed.

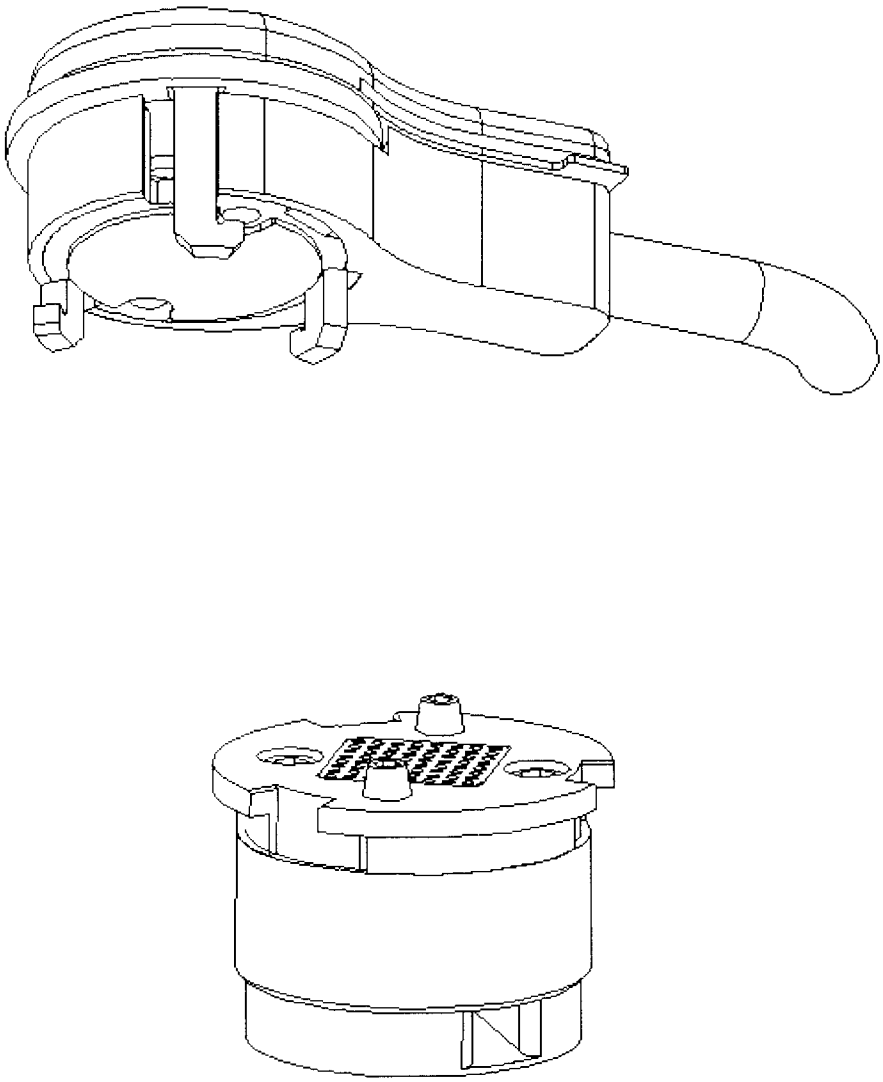


Figure 3. The lower or implantable mechanism and the upper (external) mechanism shown separately. Note the alignment features and the notched flange on the lower section and the claws on the upper section. The pin grid array (PGA) is clearly shown on the lower section, but the mating contacts of the flex circuit are not shown on the upper assembly.

V. Activities for the Next Quarter

During the next quarter:

- Complete the assemble of the quick disconnect
- Run the leakage tests on ceramic and polymer samples
- Continue leakage testing the final implants at HMRI